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Limitations on the role of vacuum-assisted closure in cardiac surgery

To the Editor:

We disagree with the conclusion of the article of Luckraz and colleagues[1] that vacuum-assisted closure (VAC) "can be used alone as acceptable treatment modality for sternal wound infection." In their series of 27 patients with postoperative mediastinitis, the intended treatment was VAC initially, but only 14 patients actually had VAC only (group A), whereas the other 13 patients had VAC followed by myocutaneous flap. Of the latter group, 8 patients underwent flap closure because "the wound was clean and granulating but too large," and 5 more underwent direct closure "because this facilitated discharge from hospital."[1] This represents a gross 50% failure of the original intended treatment and invalidates the group's conclusions.

Moreover, of the 14 patients in group A who had VAC only, only 8 had débridement of the sternum, whereas 6 did not. It is not said how many patients who died in groups A and B did not have débridement. In group A, 4 patients died (28.6%), and only 64% survived with healed scar. This in our opinion, does not represent a successful result of the VAC-only therapeutic modality.

Furthermore, 2 patients in group A had multiple organ failure. It was not said whether these 2 patients had persistent mediastinitis. Did they have débridement of the sternum?

We also believe that the incidence of mediastinitis among the patients was miscalculated by the authors, because 27 of 491 patients would be 5%, not 0.05% as stated, and in our opinion represents a rate higher than expected from reports in the literature. The incidence of mediastinitis before VAC was also miscalculated, because 13 of 310 is 4%, not 0.04% as stated.

On the basis of these data, we conclude that VAC alone was successful in a few selected cases and cannot be recommended as solitary treatment. We believe that débridement of the sternum and mediastinum is an obligatory procedure for every patient who has a deep sternal wound. Often there is accumulation of infected fibrin that needs to be completely removed, and a few patients have fragments of sternum that are devascularized and need to be excised to promote granulation and healing. We favor omental flaps rather than myocutaneous flaps after the débridement, because they are easy, quick, and successful in taking care of the deep mediastinal infection in 100% of the cases. The procedure can be done by the cardiac surgeon and also allows closure of the sternum, which is successful in about 80% of the cases.

We support the use of the VAC when the sternum redehisces after initial débridement and closure, or when the sternum needs to be removed because of devascularization. VAC is also helpful when the subcutaneous tissue does not heal after initial débridement, omental flap, and closure.

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Reference

1. Luckraz H, Murphy F, Bryant S, Charman SC, Ritchie AJ. Vacuum-assisted closure as a treatment modality for infections after cardiac surgery. *J Thorac Cardiovasc Surg*. 2003;125:301-5.

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Reply to the Editor:

We note the comments of Aru and Call. Our article[1] described our initial experience with vacuum-assisted closure (VAC) for treating sternal wound infection. It was a purely descriptive rather than comparative process, and hence the results should be interpreted likewise. The number of patients described was relatively small (27 patients), and sweeping conclusions may be misleading. However, in the population group that we described, VAC represented an acceptable treatment option relative to our previous experience. We are currently running a randomized study that will include a larger number of patients and will compare VAC with other treatment modalities.

With respect to their queries about wound débridement in group A, 14 had wound débridement, among whom 3 died (2 patients with methicillin-resistant *Staphylococcus aureus* sepsis and multiorgan failure and 1 patient with pneumonia). There was a further death in group A of a patient who did not have wound débridement, and the cause of death was peritonitis. In group B 10 patients underwent wound débridement, 1 of whom died. The 3 group B patients who did not have the wound débrided all survived. Moreover, the incidence of mediastinitis was described as a ratio, not a percentage, of 0.05 (27/491), which is equivalent to the 5% that they calculated.

We are delighted to see Aru and Call support the use of VAC in their letter, although their criteria differ from ours. However, they seem convinced that the main treatment modality for mediastinitis involves the use of an omental flap. We would be grateful if they could share their up-to-date experience, rather than the 1987 data,[1] with us.

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1. Luckraz H, Murphy F, Bryant S, Charman SC, Ritchie AJ. Vacuum-assisted closure as a treatment modality for infections after cardiac surgery. *J Thorac Cardiovasc Surg*. 2003;125:301-5.
2. Heath BJ, Bagnato VJ. Poststernotomy mediastinitis treated by omental transfer without postoperative irrigation or drainage. *J Thorac Cardiovasc Surg*. 1987;94:355-60.

doi:10.1016/j.jtcvs.2003.07.040

Reporting of clinical trials of analgesia

To the Editor:

Ott and colleagues,[1] and the editorial staff of the *Journal*, deserve much credit for carrying out and publishing a study on the use of cyclooxygenase 2 inhibitors for postoperative pain after coronary artery bypass grafting. However, the study report is beset with serious deficiencies in the presentation of the study results, which should be noted to avoid similar deficiencies in what I hope will be future publications of studies on postoperative pain relief.

Ott and colleagues[1] commendably sought to provide a risk-benefit assessment of the use of parecoxib and valdecoxib in the post–coronary artery bypass grafting setting by reporting on both the degree of pain relief and differences in adverse effects associated with the study drugs relative to the control group. The first issue is the choice of primary outcome measure: amount of reduction in morphine consumption administered by a patient-controlled analgesia (PCA) pump. Ott and colleagues[1] reported an overall reduction of morphine consumption of approximately 20% in the parecoxib/valdecoxib group relative to the placebo group. Although this may indicate a statistically significant analgesic effect, especially in light of the hints provided later about the secondary analgesic efficacy measures, the article did not discuss whether this degree of opioid sparing was clinically meaningful in this population. As has been discussed at length in multiple recent US Food and Drug Administration Advisory Committee meetings, opioid sparing alone does not necessarily imply clinical benefit. Clinical benefit of opioid sparing must be demonstrated directly, for example by showing a reduction in opioid-related side effects. In this study Ott and colleagues[1] appropriately reported relative side effects in the two treatment groups. One would hope to see a reduction in typical opioid side effects, such as nausea, vomiting, dizziness, sedation, fatigue, and constipation; however, these were numerically about the same in the two groups, with the possible exceptions of dizziness (higher in the control group) and nausea (higher in the cyclooxygenase 2 inhibitor group). Thus one cannot conclude that there was clinically meaningful benefit of the study drugs according to the primary outcome measure of the study.

Of course, in studying an analgesic the critical issue is whether pain control is improved. Although some have argued that it is unrealistic to expect reductions in pain intensity when both treatment and control groups have access to morphine PCA, in fact multiple published studies of nonopioid analgesics versus placebo in the setting of PCA have succeeded in demonstrating pain reduction. Unfortunately, Ott and colleagues[1] did not provide any interpretable pain data, which is inexcusable in a study of an analgesic for postoperative pain. They did provide data on the "peak pain intensity difference," defined as the "difference between maximum daily sternotomy pain and pretreatment sternotomy pain" calculated for each day of treatment. Given that the study drugs were administered twice a day, and that the pretreatment pain scores are not presented, the meaning of this outcome measure is unclear. Furthermore, the single figure in which these data are presented suggests that the difference between active drug and placebo was less than 1 unit on a 4-point pain intensity scale, a difference of uncertain clinical meaningfulness.

Ott and colleagues[1] did obtain data on various subscales of the Brief Pain Inventory, but they chose not to present the data. Instead, they indicated that differences in several of these subscales between groups had reached statistical significance, which does not inform the reader about the magnitude of potential clinical benefit. Although the small differences in patient and physician global assessments of study drug went in the hoped-for direction, global assessments are not a direct measure of pain.

This study report presented a thorough discussion of the disturbing safety issues associated with the cyclooxygenase 2 inhibitors; however, the data presented do not justify the conclusion that "the parecoxib/valdecoxib regimen demonstrated superiority for pain relief over an aggressive therapeutic regimen supplemented with PCA." Future reports of analgesic clinical trials should include the specific pain data obtained, not just *P* values, so that readers can decide the clinical meaningfulness of any claimed benefits. This point should be noted by both authors and by journals, who should both be encouraged to continue to foster research on postoperative analgesia.

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Reference

1. Ott E, Nussmeier NA, Duke PC, Feneck RO, Alston RP, Snabes MC, et al. Efficacy and safety of the cyclooxygenase 2 inhibitors parecoxib and valdecoxib in patients undergoing coronary artery bypass surgery. *J Thorac Cardiovasc Surg*. 2003;125:1481-92.

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